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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,918	12/13/2005	John E. Hansen	13323-105003	5673
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KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER				
HAND, MELANIE JO				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
10/21/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/538,918

Applicant(s)

HANSEN ET AL.

Examiner

MELANIE J. HAND

Art Unit

3761

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.88,91-95,97-106,118-120,130-136,138-141,143-158 and 160-164 is/are pending in the application.
- 4a) Of the above claim(s) 130-136 and 143-157 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1.88,95,141 and 158 is/are allowed.
- 6) ☒ Claim(s) 91,93,94,97-100,105,106,118-120,138-140,163 and 164 is/are rejected.
- 7) ☒ Claim(s) 92,100-104 and 160-162 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO 892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/29/10
- 4) ☐ Interview Summary (FTO 413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 29, 2010 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed April 29, 2010, with respect to the rejection(s) of claims 91, 93, 94, 97-100, 105, 118-120, 138-140, 163 and 164 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on April 29, 2010 was filed after the mailing date of the final action on January 15, 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 91, 93, 94, 97-99, 105, 138, 140 and 163 are rejected under 35 U.S.C. 102(b) as being anticipated by Gladstone (GB 697,603 A).

With respect to **claim 91**: Gladstone discloses a kit comprising the following: i) a sponge swab and a handle, namely forceps, attached to said swab, wherein said swab is a gelatin-based sponge (Page 1, lines 25-34, Page 2, lines 8-13); and ii) an agent, namely alcohol, i.e. an anti-microbial agent. (Page 1, lines 69-73)

With respect to **claim 93**: Gladstone discloses a method for collecting a target, namely tumor tissue, from a collection medium, i.e. the tumor site, comprising the following steps: i) providing a swab comprising gelatine (Page 2, lines 8-13); ii) making contact between the swab and the target by a rubbing motion to transfer said target from the collection medium to the swab (Page 1, lines 35-50); and iii) transferring said target from the swab to a transfer medium, (collectively or individually, formaldehyde, alcohol and heated molten paraffin wax), to thereby recover said target from said collection medium. (Page 1, lines 62-91)

With respect to **claim 94**: The swab disclosed by Gladstone comprises a gelatin-based sponge.
(Page 2, lines 8-13)

With respect to **claim 97**: Gladstone discloses a method for collecting a target, namely tumor tissue, from a collection medium, i.e. the tumor site, comprising the following steps: i) making contact between a swab and at least a portion of a sample area, i.e. the tumor, by a rubbing motion so that an amount of the target adheres to the swab (Page 1, lines 35-50); and ii) transferring the adhered target from the swab to a transfer medium, (collectively or individually, formaldehyde, alcohol and heated molten paraffin wax). (Page 1, lines 62-91)

With respect to **claim 98**: The collection medium or area disclosed by Gladstone is a solid or semi-solid surface, specifically a tumor site. (Page 1, lines 35-38)

With respect to **claim 99**: The target disclosed by Gladstone is tumor tissue from a human patient, i.e. a mammalian cell.

With respect to **claims 105,163**: The method disclosed by Gladstone further comprises contacting said swab with an agent, namely alcohol, an anti-microbial agent. (Page 1, lines 69-73)

With respect to **claim 138**: The swab disclosed by Gladstone comprising gelatin is attached to a support inasmuch as it is held between jaws of forceps. (Page 1, lines 25-34)

With respect to **claim 140**: The support disclosed by Gladstone is a forceps-like device and thus has a form of a handle.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 106 and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gladstone ('603) in view of Kelly (see included PTO-892 form for full citation).

With respect to **claim 106**: Gladstone only discloses visual examination of collected target tissue cells and thus does not disclose that said method further comprises culturing cells collected on the swab in a growth medium. The method disclosed by Kelly further comprises culturing cells collected on a swab in a growth medium inasmuch as Kelly discloses an operative swab culture, wherein a culture by its nature requires a growth medium to perform its intended function. As culturing allows determination of undesirable or harmful matter or cells in the target for improved diagnostic performance and treatment, it would be obvious to one of ordinary skill in the art to supplement the visual examination step of the tumor tissue specimen

disclosed by Gladstone with the step of culturing the tumor cells collected on the swab to improve the diagnostic capability of the method which may in turn improve treatment of the patient.

With respect to **claim 164**: Gladstone discloses that said target comprises cells, namely tumor tissue cells. Gladstone only discloses visual examination of collected target tissue cells and thus does not disclose that said method further comprises culturing cells collected on the swab in a growth medium. The method disclosed by Kelly further comprises culturing cells collected on a swab in a growth medium inasmuch as Kelly discloses an operative swab culture, wherein a culture by its nature requires a growth medium to perform its intended function. As culturing allows determination of undesirable or harmful matter or cells in the target for improved diagnostic performance and treatment, it would be obvious to one of ordinary skill in the art to supplement the visual examination step of the tumor tissue specimen disclosed by Gladstone with the step of culturing the tumor cells collected on the swab to improve the diagnostic capability of the method which may in turn improve treatment of the patient.

9. Claims 100 and 118-120 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gladstone ('603).

With respect to **claim 100**: It is the examiner's position that, while Gladstone discloses a target that is a mammalian cell rather than an organic molecule, the method is fully capable of use in collecting organic molecules as a target for microscopic visual examination as disclosed by Gladstone, wherein the organic molecule is selected from the group consisting of a nucleotide, a nucleic acid, a protein and a detergent. It is axiomatic that one who performs the steps of a

process must necessarily produce all of its advantages. Mere recitation of a newly discovered property or function that is inherently possessed by the things or steps in the prior art does not cause a claim drawn to those things to distinguish over the prior art. *Leinoff v. Louis Milona & Sons, Inc.* 220 USPQ 845 (CAFC 1984)

With respect to **claim 118**: It is the examiner's position that, while Gladstone discloses use of the method to collect tumor tissue, the method is fully capable of use in collecting microorganisms for microscopic visual examination as disclosed by Gladstone, wherein the micro-organism is selected from the group consisting of bacteria, bacterial spores, archaea, yeast and fungi. It is axiomatic that one who performs the steps of a process must necessarily produce all of its advantages. Mere recitation of a newly discovered property or function that is inherently possessed by the things or steps in the prior art does not cause a claim drawn to those things to distinguish over the prior art. *Leinoff v. Louis Milona & Sons, Inc.* 220 USPQ 845 (CAFC 1984)

With respect to **claims 119,120**: It is the examiner's position that, since Gladstone discloses use of the method to collect tumor tissue, a type of mammalian cell, the method is fully capable of use in collecting a mammalian cell that is a cell from blood plasma, wherein the mammalian cell is selected from the group consisting of leukocytes, erythrocytes and thrombocytes. It is axiomatic that one who performs the steps of a process must necessarily produce all of its advantages. Mere recitation of a newly discovered property or function that is inherently possessed by the things or steps in the prior art does not cause a claim drawn to those things to distinguish over the prior art. *Leinoff v. Louis Milona & Sons, Inc.* 220 USPQ 845 (CAFC 1984)

10. Claim 139 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gladstone ('603).

With respect to **claim 139**: Gladstone discloses that said support is a forceps-like device and that the "handle and the jaw are made tubular". Therefore while Gladstone does not disclose any particular materials, it is the examiner's position that this quoted phrase fairly suggests synthetic polymer material. Since synthetic polymer material would also be inert with respect to both the swab material and the collected tumor tissue, it would be obvious to one of ordinary skill in the art to modify the method disclosed by Gladstone such that the support comprises a synthetic polymeric material, e.g. plastics with a reasonable expectation of success to provide a durable but inert support material.

Allowable Claims

11. Claims 1, 88, 95, 141, 158 are allowed.
12. Claims 92, 100-104 and 160-162 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

13. The following is an examiner's statement of reasons for indicating allowable subject matter:

- a. With respect to claim 92, Gladstone discloses immersing the sponge in formaldehyde and alcohol and discloses applying the sponge to the tumor site in a dry condition. Therefore, Gladstone does not disclose or suggest a neutral diluent. From this, it would not be obvious to one of ordinary skill in the art to first modify the kit of Gladstone such that the agent is a neutral diluent and then further modify the resulting kit such that said neutral diluent is selected from the group consisting of saline, saline peptone, buffered saline peptone, Ringer solution and an organic or inorganic buffer.
- b. With respect to claims 101 and 161, the transferring step in the method disclosed by Gladstone does not employ an enzyme or any substance capable of digesting the gelatin sponge material, and in fact Gladstone discloses encasing the sponge as is in wax for easier slicing for microscopic examination. It is the examiner's position that this disclosure teaches away from any action involving any disintegration of the sponge, including digestion of the gelatin sponge. Thus Gladstone does not disclose or suggest that the transferring step includes digestion of said gelatine. Claims 103 and 104 depend from claim 101 and are thus also directed to allowable subject matter.
- c. With respect to claims 102 and 162, Gladstone explicitly discloses killing and hardening the tumor tissue target on the swab to fix the specimen on the swab and discloses subsequently immersing the swab in alcohol or acetone or the like to dehydrate the swab and immersing the swab in molten wax to harden the swab for easier slicing as is. The Gladstone disclosure is clear that no target cells are to be washed or otherwise transferred from the swab prior to examination. Therefore

Gladstone does not disclose or suggest a transferring step that includes washing said target from the swab.

d. With respect to claim 160, Gladstone explicitly discloses that the swab is applied to the target collection medium or area in a dry condition and thus does not disclose, and teaches away from, a swab that is pre-wetted.

Reasons for Allowance

14. The following is an examiner's statement of reasons for allowance:

e. With respect to claim 1, Gladstone does not disclose or suggest a device comprising a sterile sponge swab and a handle attached to said swab, wherein said swab is a gelatin-based sponge, and wherein said device is contained in a sealed package. Gladstone discloses forceps attached to a swab and it is known in the art to package forceps in a package, however since Gladstone does not disclose a package for either the gelatin sponge swab or the forceps, it would not be obvious to one of ordinary skill in the art to have the device contained in a sealed package. Claim 88 depends from claim 1 and is thus also allowed

f. Claims 95, 141 and 158 were allowed for reasons stated in detail in the final action mailed January 15, 2010.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761